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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/727,734   | 12/04/2003  | Jane F. Koretz       | RPI-3731            | 7208             |
| 5409   | 7590        | 09/27/2005           | EXAMINER            |                  |
| ARLEN L. OLSEN<br>SCHMEISER, OLSEN & WATTS<br>3 LEAR JET LANE<br>SUITE 201<br>LATHAM, NY 12110 |             |                      | SANDERS JR, JOHN R  |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 3737                 |                     |                  |
| DATE MAILED: 09/27/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 10/727,734      | KORETZ, JANE F. |
|                              | Examiner        | Art Unit        |
|                              | John R. Sanders | 3737            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 June 2005.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 04 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1, 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent No. 101 54 194 A1 to Vogelsang et al (“Vogelsang”).**

4. For the following rejection, reference is made to U.S. Patent Application Publication No. 2005/0041206 A1, which suffices as an English language translation of the German Patent to Vogelsang.

5. Re claims 1 and 7: Vogelsang discloses a method and device for measuring the dynamic behavior of the eye wherein wavefront imaging of the eye is performed during dynamic accommodative stimulation (paragraph 9-10). The device of Vogelsang comprises an accommodative stimulation device (fig. 3, ref. 10) comprising adjustable fixation target 12 and Badal lens 8 (paragraph 23, 35); and a wavefront aberrometer 1 synchronized with the stimulation device such that “the measured adaptation processes of the eye [can] be directly

associated with the particular stimulus and its variation over time" (paragraph 13). Vogelsang obviates an accommodative stimulation device that simultaneously stimulates and eye to undergo an accommodative transition from one state to another while acquiring imaging information about the eye.

Vogelsang discloses reflecting the beam path of the stimulation unit into the path of the aberrometer (paragraph 19) but does not expressly disclose a half-silvered mirror. However half-silvered mirror beam splitters are common expedients in the art for combining beam paths and as such would have been obvious to one of ordinary skill in the art to use to combine beam paths in the device of Vogelsang.

6. Re claim 2: Vogelsang does not expressly disclose the first and second accommodative states being selectable from the entire range of accommodation of the eye. However, it is inherent to the dynamic measurement of the accommodation of the eye that the initial and final accommodative states through which the eye adjusts focus during measurement would necessarily fall within the range of possible accommodation for the eye. Furthermore, Badal optometers, which are known in the art, are desirably designed to effect accommodative changes in the eye through the entire possible range of accommodation of the eye's lens.

7. **Claims 3-5, 13, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelsang, as applied to claim 1 above, and further in view of U.S. Patent No. 4,778,268 to Randle ("Randle") and U.S. Patent No. 6,419,671 to Lemberg ("Lemberg").**

8. Re claims 3, 4, 13, 14 and 16: Vogelsang discloses a variable intensity/focus fixation target as previously discussed but does not expressly disclose: a set of exchangeable target-

image-forming masks within the projection apparatus (i.e., the accommodative stimulation unit **10**) or a computer-controlled motorized carriage for moving the projection systems along a linear scale.

Randle teaches an accommodation tester that is effective in stimulating the accommodation of the eye by projecting a visual target through Badal optics, and is analogous to the accommodative stimulation unit disclosed by Vogelsang. Randle is exemplary of an optometer with Badal optics expressly designed to effect accommodative changes in the eye in a manner well known to artisans of ordinary skill. Randle teaches illuminated target projection optics disposed on a translatable stage **20** that can be driven by a computer-controlled motor and which has a linear diopter scale **23** disposed thereon (fig. 23; col. 4, lines 55-64). Randle also teaches several apertures that are interchangeable in the optical path effecting different operability (col. 5, lines 29-53) and which serve to form the image of the target.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to incorporate the accommodation-stimulating device of Randle, including the exchangeable target-image-forming masks, computer-controlled motorized stage and linear scale, into the device of Vogelsang to serve as the accommodative stimulation unit therein, as the device of Randle serves the same express purpose of the accommodative stimulation unit, i.e. to cause the eye to adapt through a range of accommodation.

Vogelsang does not expressly disclose a system of adjustable lenses for correcting a refractive error of the eye. Lemberg teaches a diagnostic/surgical system for ophthalmology that includes a fixation target path. Lemberg teaches a fixation target optical path **238** with adjustable lens elements **240** disposed therein for purposes of refractive correction such that the

fixation target is clearly viewed by the subject (col. 12, lines 1-21). This correction is effected in a manner well known in the art and is also commonly effected by the functional equivalents of an alterable path length element or a pair of rotatable cylindrical lenses. Adjustable lenses as claimed would be obvious to an artisan of ordinary skill as a common expedient to include in any ophthalmic instrument wherein a fixation target is projected to the eye and meant to be viewed in focus by the eye.

9. Re claim 5: Vogelsang in view of Randle and Lemberg does not expressly teach that the computer-controlled motorized carriage is moveable within a period of time substantially less than a minimum response time for full accommodation. However, Vogelsang does teach the dynamic imaging of the eye and that “[t]he optical action during stimulation may be modulated either abruptly or continuously” (paragraph 45). One of ordinary skill in the art, reading the disclosure of Vogelsang, would understand that for continuous dynamic imaging of the accommodative function of the eye, the stimulus must be operable to change the focus of the eye faster than the eye can achieve a full, fixed accommodation at a singular focal point. In other words, to keep the eye from achieving a series of discrete accommodative states during stimulation, the stimulus must continuously move through focus fast enough for discrete accommodation to not occur. Examiner submits that the device of Vogelsang, though not explicitly stated, is in fact capable of this motion and/or one of ordinary skill in the art would find it obvious to achieve said motion based upon the aforementioned disclosure of Vogelsang.

**10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelsang in view of Randle and Lemberg as applied to claim 13 above, and further in view of U.S. Patent No. 5,757,462 to Nanjo (“Nanjo”).**

Vogelsang in view of Randle and Lemberg, as discussed above, teaches the dynamic imaging of the eye through an accommodative range with respect to wavefront aberrometry measurement. The combination does not expressly dynamically imaging the eye with a Scheimpflug videography device during accommodative stimulation.

Nanjo clearly teaches a slit-lamp apparatus for imaging the anterior chamber of the eye based on the Scheimpflug principle. Nanjo is analogous art to Vogelsang as Nanjo teaches a device designed to image the eye, specifically the area of the eye affected by accommodative change, and Vogelsang expressly discloses dynamic stimulation of the accommodative function of the eye and the synchronous acquiring of imaging information from the eye.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, when viewing the disclosures of Vogelsang and Nanjo, to use a Scheimpflug imaging device as a means for acquiring image information during dynamic accommodative stimulation in place of the wavefront aberrometer expressly disclosed by Vogelsang, since one of ordinary skill in the art would be apprised that Scheimpflug imaging is a known expedient in the art for imaging the anterior chamber of the eye, the area within the eye where the crystalline lens (the element which effects accommodative change) is disposed, and since Vogelsang expressly discloses acquiring dynamic measurements of the eye through accommodative stimulation.

11. **Claims 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelsang in view of Nanjo.**

12. Re claims 6 and 8: Vogelsang, as discussed above, discloses the dynamic imaging of the eye through an accommodative range with respect to wavefront aberrometry measurement. Vogelsang does not expressly disclose dynamically imaging the eye with a Scheimpflug videography device during accommodative stimulation.

Nanjo clearly teaches a slit-lamp apparatus for imaging the anterior chamber of the eye based on the Scheimpflug principle. Nanjo is analogous art to Vogelsang as Nanjo teaches a device designed to image the eye, specifically the area of the eye affected by accommodative change, and Vogelsang expressly discloses dynamic stimulation of the accommodative function of the eye and the synchronous acquiring of imaging information from the eye.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, when viewing the disclosures of Vogelsang and Nanjo, to use a Scheimpflug imaging device as a means for acquiring image information during dynamic accommodative stimulation in place of the wavefront aberrometer expressly disclosed by Vogelsang, since one of ordinary skill in the art would be apprised that Scheimpflug imaging is a known expedient in the art for imaging the anterior chamber of the eye, and since Vogelsang expressly discloses acquiring dynamic measurements of the eye through accommodative stimulation.

13. Re claim 9: Vogelsang does not expressly disclose the first and second accommodative states being selectable from the entire range of accommodation of the eye. However, it is inherent to the dynamic measurement of the accommodation of the eye that the initial and final accommodative states through which the eye adjusts focus during measurement would

necessarily fall within the range of possible accommodation for the eye. Furthermore, Badal optometers, which are known in the art, are desirably designed to effect accommodative changes in the eye through the entire possible range of accommodation of the eye's lens.

**14. Claims 10, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelsang in view of Nanjo as applied to claim 8 above, and further in view of Lemberg and Randle.**

15. Vogelsang in view of Nanjo teaches dynamic imaging with a Scheimpflug videography system as previously discussed, but does not expressly teach the limitations of a set of exchangeable target-image-forming masks within the projection apparatus, a computer-controlled motorized carriage for moving the projection systems along a linear scale or a system of adjustable lenses for correcting a refractive error of the eye.

As previously discussed with respect to claims 3, 4, 13, 14 and 16 above, the teachings of Randle and Lemberg obviate these limitations in an accommodative stimulus-presenting device. Thus, it would be obvious to one of ordinary skill in the art to use the accommodative stimulation device of Vogelsang in view of Lemberg and Randle for stimulating the accommodation of the eye during Scheimpflug imaging, as taught by Nanjo.

**16. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randle in view of Lemberg.**

Randle discloses an accommodation tester that is effective in stimulating the accommodation of the eye by projecting a visual target through Badal optics. Randle discloses

illuminated target projection optics disposed on a translatable stage **20** that can be driven by a computer-controlled motor and which has a linear diopter scale **23** disposed thereon (fig. 23; col. 4, lines 55-64). Randle also teaches several apertures that are interchangeable in the optical path effecting different operability (col. 5, lines 29-53) and which serve to form the image of the target.

Randle does not expressly disclose a system of adjustable lenses for correcting a refractive error of the eye. Lemberg teaches a diagnostic/surgical system for ophthalmology that includes a fixation target path. Lemberg teaches a fixation target optical path **238** with adjustable lens elements **240** disposed therein for purposes of refractive correction such that the fixation target is clearly viewed by the subject (col. 12, lines 1-21). This correction is effected in a manner well known in the art and is also commonly effected by the functional equivalents of an alterable path length element or a pair of rotatable cylindrical lenses. Adjustable lenses as claimed would be obvious to an artisan of ordinary skill. Therefore, it would have been obvious to one of ordinary skill in the art to modify Randle to include adjustable lens elements for refractive correction as adjustable lenses are common expedients in ophthalmic instrument wherein a fixation target is projected to the eye and meant to be viewed in focus by the eye, as taught by Lemberg.

**17. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randle in view of Lemberg as applied to claim 17 above, and further in view of Vogelsang.**

**18. Randle in view of Lemberg does not expressly teach that the computer-controlled motorized carriage is moveable within a period of time substantially less than a minimum**

response time for full accommodation. However, Vogelsang teaches the dynamic imaging of the eye and that “[t]he optical action during stimulation may be modulated either abruptly or continuously” (paragraph 45). One of ordinary skill in the art, reading the disclosure of Vogelsang, would understand that for continuous dynamic imaging of the accommodative function of the eye, the stimulus must be operable to change the focus of the eye faster than the eye can achieve a full, fixed accommodation at a singular focal point. In other words, to keep the eye from achieving a series of discrete accommodative states during stimulation, the stimulus must continuously move through focus fast enough for discrete accommodation to not occur. At the time of the invention, one of ordinary skill in the art would find it obvious to achieve this continuous motion with the device taught by Randle in view of Lemberg, based upon the teaching of Vogelsang.

### *Conclusion*

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Sanders whose telephone number is (571) 272-4742. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
3~~8~~September 2005